



## DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

**Manufacturer:** BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.

**Address:** No. 7, Yan Qi He, Xi Yi Rd., Huai Rou District, Beijing, China.

**European Representative:** Lotus NL B.V.

**Contact person:** Peter E-mail: peter@lotusnl.com

**Address:** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

### In Vitro Diagnostic Directive:

- Multiple Real-Time PCR kit for Detection of SARS-CoV-2.

**Category:** Others.

**Conformity assessment route:** Declaration of Conformity IVDD Annex III

### Applicable Standards:

ISO13485:2016

ISO 14971:2019

ENISO18113-1:2011

ENISO18113-2:2011

ENISO18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO23640:2015

EN 62366-1:2015

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Place Beijing, China

**European Representative:**

Seal/Stamp:

Lotus NL B.V.



**Name of authorized signatory:**

**Position held in the company:** General Manager

Seal/Stamp:

BEIJING KEWEI CLINICAL

DIAGNOSTIC REAGENT INC.

*Wang Baoguo*  
26/10.2021